

# **NARCAN<sup>®</sup>** (naloxone HCl) **NASAL SPRAY 4mg**

## **INFORMATION FOR PHARMACISTS**

Do you see patients  
at risk of an opioid  
overdose?



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### **NARCAN<sup>®</sup> NASAL SPRAY INDICATIONS AND IMPORTANT SAFETY INFORMATION**

#### **INDICATIONS**

NARCAN<sup>®</sup> (naloxone hydrochloride) Nasal Spray is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. NARCAN<sup>®</sup> Nasal Spray is intended for immediate administration as emergency therapy in settings where opioids may be present.

NARCAN<sup>®</sup> Nasal Spray is not a substitute for emergency medical care.

#### **IMPORTANT SAFETY INFORMATION**

NARCAN<sup>®</sup> Nasal Spray is contraindicated in patients known to be hypersensitive to naloxone hydrochloride. Seek emergency medical assistance immediately after initial use, keeping the patient under continued surveillance.

**Please see additional Important Safety Information on  
subsequent pages.**





## OPIOID OVERDOSE EPIDEMIC

The United States is in the midst of an epidemic of prescription opioid overdoses.<sup>1</sup> As a pharmacist, you are essential in educating appropriate patients who may be at risk on the availability of naloxone, which can be accessed at the pharmacy.

The amount of opioids prescribed and sold in the US has quadrupled since 1999.<sup>2</sup> The Centers for Disease Control and Prevention reported 47,055 drug overdose deaths in the US in 2014, with more than 60% of those deaths involving prescription narcotics.<sup>3</sup>

Having an adequate dose of naloxone administered in time has saved many lives. From 1996 through June 2014, organizations who provided naloxone kits to laypersons recorded more than 26,000 opioid overdose reversals in the US.<sup>4</sup>

Many states are gradually making naloxone more available in the community. The pharmacists' essential role as medication safety specialists is to protect patients and the public from unintended effects from medications.<sup>5</sup> You are positioned to help educate patients and caregivers on safe opioid use, accidental overdose, and naloxone availability.

### IMPORTANT SAFETY INFORMATION

Risk of Recurrent Respiratory and CNS Depression: Due to the duration of action of naloxone relative to the opioid, keep the patient under continued surveillance and administer repeat doses of naloxone using a new nasal spray with each dose, as necessary, while awaiting emergency medical assistance.

Risk of Limited Efficacy with Partial Agonists or Mixed Agonists/Antagonists: Reversal of respiratory depression caused by partial agonists or mixed agonists/antagonists, such as buprenorphine and pentazocine, may be incomplete. Larger or repeat doses may be required.

## RISK FACTORS

Before starting and periodically during continuation of opioid therapy, healthcare professionals should evaluate risk factors for opioid-related harms. Incorporate into the management plan strategies to mitigate risk, including offering naloxone when the following factors that increase risk for opioid overdose are present:<sup>\*6,7</sup>

- Use of prescription opioids, especially doses  $\geq 50$  morphine milligram equivalents MME/daily
- Use of opioids in combination with other sedating substances, such as benzodiazepines
- A suspected or confirmed history of substance abuse, dependence or non-medical use of prescription or illicit opioids

For these patients, **recommend that an emergency treatment for opioid overdose be in their home or with a caregiver/loved one.**

\*Adapted from World Health Organization: Substance Abuse Information Sheet on Opioid Overdose, 2014, and Centers for Disease Control and Prevention: CDC Guideline for Prescribing Opioids for Chronic Pain, 2014.

### IMPORTANT SAFETY INFORMATION

Precipitation of Severe Opioid Withdrawal: Use in patients who are opioid dependent may precipitate opioid withdrawal characterized by body aches, fever, sweating, runny nose, sneezing, goose bumps (piloerection), yawning, weakness, shivering or trembling, nervousness, restlessness or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure and increased heart rate (tachycardia). In some patients, there may be aggressive behavior upon abrupt reversal of an opioid overdose. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated and may be characterized by convulsions, excessive crying, and hyperactive reflexes. Monitor for the development of opioid withdrawal.

**Please see additional Important Safety Information on subsequent pages.**

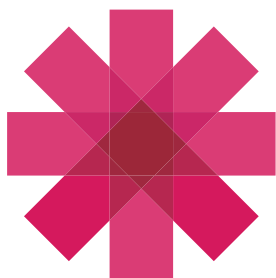


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## STARTING THE CONVERSATION

The word “overdose” can have a negative connotation and patients who take prescription opioids may not relate to it, or think it could not happen to them. When talking to patients, consider using language like “accidental overdose.” You may also consider saying:<sup>8,9</sup>

- “Opioids can sometimes slow or even stop your breathing”
- “Naloxone can help reverse an opioid overdose - it can be administered intranasally if you accidentally take too much and can’t be woken up”
- “Family members, caregivers, or other people who may have to use NARCAN<sup>®</sup> Nasal Spray in an opioid emergency should know where NARCAN<sup>®</sup> Nasal Spray is stored and how to give NARCAN<sup>®</sup> before an emergency happens”
- “NARCAN<sup>®</sup> is not a substitute for emergency medical care; it is important to get emergency medical help right away after giving the first dose. Repeated doses may be necessary”



## IMPORTANT SAFETY INFORMATION

Risk of Cardiovascular (CV) Effects: Abrupt postoperative reversal of opioid depression may result in adverse CV effects. These events have primarily occurred in patients who had pre-existing CV disorders or received other drugs that may have similar adverse CV effects. Monitor these patients closely in an appropriate healthcare setting after use of naloxone hydrochloride.

The following adverse reactions were observed in a NARCAN Nasal Spray clinical study: increased blood pressure, constipation, toothache, muscle spasms, musculoskeletal pain, headache, nasal dryness, nasal edema, nasal congestion, nasal inflammation, rhinalgia, and xeroderma.

## WHAT IS NARCAN<sup>®</sup> NASAL SPRAY 4mg?

NARCAN<sup>®</sup> (naloxone HCl) Nasal Spray is the first and only FDA-approved nasal form of naloxone for the emergency treatment of a known or suspected opioid overdose.<sup>9</sup>

NARCAN<sup>®</sup> Nasal Spray counteracts the life-threatening effects of opioid overdose.<sup>9</sup> Making naloxone available in the home setting provides the opportunity for family members, friends or caregivers to intervene with this potentially life-saving medication.<sup>10,11</sup>

### NARCAN<sup>®</sup> Nasal Spray:

- Designed for ease-of-use\*
- Has a 4 mg concentrated dose
- Needle-free
- Requires no specialized training\*<sup>12</sup>

Not a substitute for emergency medical care. Repeated doses may be necessary.

\*Administer in accordance with the Instructions for Use.

NARCAN<sup>®</sup> Nasal Spray is contraindicated in patients known to be hypersensitive to naloxone hydrochloride. Seek emergency medical assistance immediately after initial use, keeping the patient under continued surveillance.

## IMPORTANT SAFETY INFORMATION

See Instructions for Use and full Prescribing Information in the use of this product, available here: <http://www.narcan.com/pdf/NARCAN-Prescribing-Information.pdf>.

Additional information, including full Prescribing Information for NARCAN<sup>®</sup> Nasal Spray, and Important Safety Information and Instructions for Use, is also available at [www.NARCAN.com](http://www.NARCAN.com).

To report SUSPECTED ADVERSE REACTIONS, contact Adapt Pharma, Inc. at 1-844-4NARCAN (1-844-462-7226) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

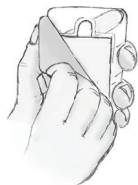
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# **NARCAN<sup>®</sup>** (naloxone HCl) **NASAL SPRAY 4mg**

## KEY STEPS TO ADMINISTRATION\*

### PEEL



Peel back the package to remove the device. Hold the device with your thumb on the bottom of the plunger and 2 fingers on the nozzle.

### PLACE



Place and hold the tip of the nozzle in either nostril until your fingers touch the bottom of the patient's nose.

### PRESS



Press the plunger firmly to release the dose into the patient's nose.

**\*Administer in accordance with the Instructions for Use. Repeated doses may be necessary.**

NARCAN<sup>®</sup> Nasal Spray is not a substitute for emergency medical care. When administering NARCAN<sup>®</sup> Nasal Spray, call 911 right away, even if the person wakes up. Keep the patient under surveillance or close watch.

## IMPORTANT SAFETY INFORMATION

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Risk of Recurrent Respiratory and CNS Depression: Due to the duration of action of naloxone relative to the opioid, keep the patient under continued surveillance and administer repeat doses of naloxone using a new nasal spray with each dose, as necessary, while awaiting emergency medical assistance.

Risk of Limited Efficacy with Partial Agonists or Mixed Agonists/Antagonists: Reversal of respiratory depression caused by partial agonists or mixed agonists/antagonists, such as buprenorphine and pentazocine, may be incomplete. Larger or repeat doses may be required.

## OBTAINING NARCAN<sup>®</sup> NASAL SPRAY 4mg

State-specific regulations regarding naloxone vary significantly. In many states, residents can purchase directly from a pharmacist under a state Standing Order or Collaborative Practice Order. NARCAN<sup>®</sup> Nasal Spray is available through most major distributors or you can contact Adapt Customer Service at: (1-844-4NARCAN) or 844-462-7226.

NARCAN <sup>®</sup> Nasal Spray	NDC # 69547-0353-02
Wholesaler	Item #
Amerisource Bergen	10162640
Cardinal	5204037
H.D. Smith	5525191
McKesson	3519402

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## HOW TO EDUCATE PATIENTS ON NALOXONE

Pharmacists are an important resource to help educate appropriate, at-risk patients taking prescription opioids.

You and your staff can educate patients about naloxone and its availability. Education generally includes:<sup>8</sup>

- Informing patients about the pharmacologic properties of naloxone
- When to administer naloxone
- How to administer naloxone
- Informing patients to alert others about the medication, how to use it and where it's kept, as it is generally not self-administered
- Discussing the red-flag symptoms that indicate opioid overdose
- Discussing that the following adverse reactions were observed in a NARCAN® Nasal Spray clinical study: increased blood pressure, constipation, toothache, muscle spasms, musculoskeletal pain, headache, nasal dryness, nasal edema, nasal congestion, nasal inflammation, rhinalgia, and xeroderma

### IMPORTANT SAFETY INFORMATION

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## RECOGNITION OF OPIOID OVERDOSE

Inform patients and their family members, friends or caregivers about how to recognize the signs and symptoms of an opioid overdose:<sup>9</sup>

- Snoring, gasping, or gurgling
- Blue or purple fingernails or lips
- Extreme somnolence - inability to awaken a patient verbally or upon a firm sternal rub
- Respiratory depression - this can range from slow or shallow respiration to no respiration in a patient unable to awaken

Other signs and symptoms that may accompany somnolence and respiratory depression include the following:

- Miosis
- Bradycardia and/or hypotension

Advise the patient, family members or caregivers to read the Patient Information section in the NARCAN® Nasal Spray full Prescribing Information.

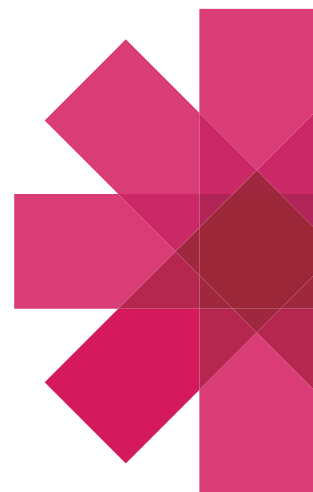
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## RECOGNITION OF OPIOID WITHDRAWAL AFTER RECEIVING NALOXONE

Patients should be aware that in some patients, especially those with opioid dependence, there may be aggressive behavior upon abrupt reversal of opioid overdose. Naloxone may cause serious side effects, including sudden opioid withdrawal symptoms. In someone who has been using opioids regularly, opioid withdrawal symptoms can happen suddenly after receiving naloxone and may include:<sup>9</sup>

- Body aches
- Diarrhea
- Increased heart rate
- Fever
- Runny nose
- Sneezing
- Goose bumps
- Sweating
- Yawning
- Nausea or vomiting
- Nervousness
- Restlessness or irritability
- Shivering or trembling
- Stomach cramping
- Weakness
- Increased blood pressure

The severity and duration of withdrawal depend on the naloxone dose, as well as the patient's type and severity of opioid dependence.

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## INSURANCE COVERAGE FOR NARCAN<sup>®</sup> NASAL SPRAY

- 94% of insured lives in the U.S. have coverage for NARCAN<sup>®</sup> Nasal Spray\*
- Nearly 73% of prescriptions for NARCAN<sup>®</sup> Nasal Spray have a co-pay of \$10 or less†

\*MMIT Formulary Analytics. Accessed March 2017

†IMS Health, NPA Extended Insights Audit. Accessed March 2017



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### INDICATIONS

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**References:** 1. Prescription painkiller overdoses in the US. [cdc.gov/vitalsigns/PainkillerOverdoses/index.html](http://cdc.gov/vitalsigns/PainkillerOverdoses/index.html). Accessed March 2017. 2. Centers for Disease Control and Prevention. Wide-ranging online data for epidemiologic research (WONDER). Atlanta, GA: CDC, National Center for Health Statistics; 2016. Available at <http://wonder.cdc.gov>. 3. Increases in drug and opioid overdose deaths—United States, 2000–2014. [cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm?s\\_cid=mm6450a3\\_w](http://cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm?s_cid=mm6450a3_w). Accessed March 2017. 4. Wheeler E, Jones S, Gilbert M, et al. Opioid Overdose Prevention Programs Providing Naloxone to Laypersons — United States, 2014. Morbidity and Mortality Weekly Report. Centers for Disease Control and Prevention Website. 2015;64(23):631–635. 5. Opioids, naloxone, and beyond: The intersection of medication safety, public health, and pharmacy. Journal of the American Pharmacists Association; 2017. Available at [http://www.japha.org/article/S1544-3191\(17\)30034-1/abstract](http://www.japha.org/article/S1544-3191(17)30034-1/abstract). 6. World Health Organization. Substance Abuse Information Sheet on Opioid Overdose: [http://www.who.int/substance\\_abuse/information-sheet/en/](http://www.who.int/substance_abuse/information-sheet/en/). Accessed February 2017. 7. CDC Guideline for Prescribing Opioids for Chronic Pain. [https://www.cdc.gov/drugoverdose/pdf/guidelines\\_at-a-glance-a.pdf](https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf). Accessed February 2017. 8. San Francisco Department of Public Health. Naloxone for opioid safety. January 2015. 9. NARCAN® Nasal Spray [Prescribing Information]. Radnor, PA. Adapt Pharmaceuticals; 2017. 10. Wermeling D. Review of naloxone safety for opioid overdose: practical considerations for new technology and expanded public access. *Ther Adv Drug Saf*. 2015 Feb;6(1):20–31. 11. Preventing opioid overdose deaths with take-home naloxone. <http://www.emcdda.europa.eu/system/files/publications/2089/TDXD15020ENN.pdf>. Accessed March 2017. 12. Krieter P, Chiang N, Gyaw S, et al. Pharmacokinetic properties and human use characteristics of an FDA-approved intranasal naloxone product for the treatment of opioid overdose. *J Clin Pharmacol*. 2016;56(10):1243–1253.



# **NARCAN<sup>®</sup>** (naloxone HCl) **NASAL SPRAY 4mg**

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- **Concentrated 4 mg dose**
- **Needle-free and designed for ease-of-use\***
- **Broad access and affordability<sup>†</sup>**



**Not a substitute for emergency medical care.**

**Repeated doses may be necessary.**

\* Administer in accordance with the Instructions for Use.

<sup>†</sup> Based on insurance coverage and retail access data from IMS Health and MMIT Formulary Analytics. Accessed March 2017.

If you have questions or would like patient education materials, please contact our customer service department at **1 (844) 462-7226**.

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